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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,151	09/20/2005	Richard Melville France	113046-003UTL	1048

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PROCOPIO, CORY, HARGREAVES & SAVITCH LLP
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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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04/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@procopio.com
PTONotifications@procopio.com

Office Action Summary	Application No. 10/550,151	Applicant(s) FRANCE ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

This restriction requirement replaces the restriction requirement mailed 4/1/08.

Claims in the case are 1-33 entered in the PCT application of
5 which the present application is a 371, and not claims 1-30 in the
restriction requirement mailed 4/1/08.

This application contains the following inventions or groups of
inventions which are not so linked as to form a single general
inventive concept under PCT Rule 13.1.

10 In accordance with 37 CFR 1.499, applicant is required, in reply
to this action, to elect a single invention to which the claims must
be restricted.

Group I, claim(s) 1-18, drawn to tissue scaffold which comprises
a porous matrix comprising a solid or semi-solid first phase and,
15 contained within and distributed through the first phase, a second
phase which optionally containing cells.

Group II, claim(s) 19-33, drawn to a process for the production
of the tissue scaffold of claim 1 which comprises bringing a first
20 phase into a fluid state, introducing a second phase into the first
phase, mixing the first and second phases such that the second phase
is contained within and distributed through the first phase, and
allowing the first phase to solidify to a solid or semi-solid state
with the second phase contained within and distributed through the
25 first phase.

The inventions listed as Groups I and II do not relate to a
single general inventive concept under PCT Rule 13.1 because, under
PCT Rule 13.2, they lack the same or corresponding special technical
30 features for the following reasons:

The special technical feature of invention I is a tissue scaffold
comprising a porous matrix comprising a solid or semi-solid first
phase and a second phase contained within and distributed through the
35 first phase.

Art Unit: 1657

The special technical feature of invention II is a process for producing the tissue scaffold of claim 1, which comprises bringing a first phase into a fluid state, introducing a second phase into the first phase, mixing the first and second phases such that the second phase is contained within and distributed through the first phase, and allowing the first phase to solidify to a solid or semi-solid state with the second phase contained within and distributed through the first phase.

Inventions I and II as claimed are different such that each does not require the other. The process of invention II can produce a tissue scaffold different than required by invention I, and the tissue scaffold of invention I can be produced by a process different than required by invention II. The tissue scaffold of invention I can be made by providing a first porous solid phase and allowing the solid phase to absorb the second phase in a fluid or suspension state, without bringing the first phase into a fluid state, mixing the first and second phases, and allowing the first phase to solidify to a solid or semi-solid state. The process of invention II can produce a tissue scaffold as required by claim 21 where particles of the first phase coat particulate material of the second phase, which is not required by invention I. Additionally, the process of invention II can be performed partially *in vivo* as required by claim 31, whereas the tissue scaffold of invention I can be produced entirely *in vitro*. Reciting in line 1 of claim 19 that the process is for producing the tissue scaffold of claim 1 does not limit the process to producing only the tissue scaffold claim 1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP §

821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a**
5 **loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
15 the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be
obtained from the Patent Application Information Retrieval (PAIR)
system. Status information for published applications may be obtained
from either Private PAIR or Public PAIR. Status information for
5 unpublished applications is available through Private PAIR only. For
more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
[direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private
PAIR system, contact the Electronic Business Center (EBC) at 866-217-
9197 (toll-free). If you would like assistance from a USPTO Customer
10 Service Representative or access to the automated information system,
call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit
1657

15 DMN
4/2/08